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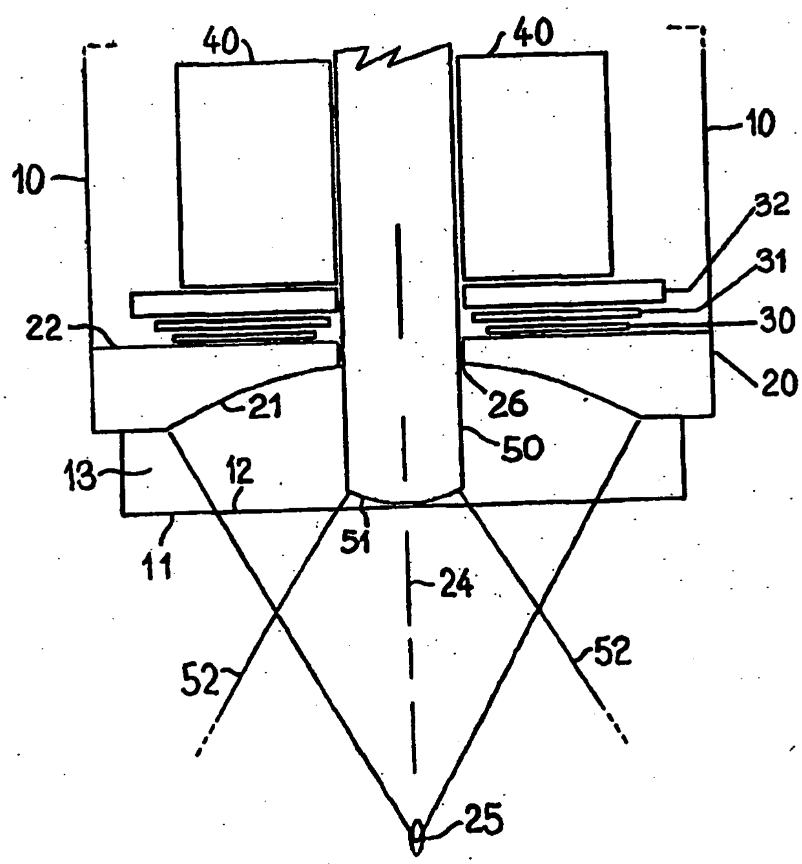
(57) Abstract

An apparatus for non-invasive tissue destruction by means of ultrasound, also called pyrotherapy. Ultrasound generating piezoelectric elements emit ultrasound which is focused by focusing means, e.g. a lens, in an external focal zone into a body to be treated. Power amplifier modules, which supply the piezoelectric elements with electric energy, are incorporated in the ultrasound head.



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Apparatus for non-invasive tissue destruction by means of ultrasound

The invention concerns an apparatus for non-invasive tissue destruction by focused high intensity ultrasound by means of which the tissue in the focal zone of the apparatus is heated to such a high temperature that the tissue is destroyed.

This therapy is called pyrotherapy and is used for localized strong heating of small tissue areas with a view to performing localized tissue destruction of e.g. tumours. In this therapy, the treated tissue is typically heated to a temperature which is higher than 60 ^{o}C.

Ultrasound for medical diagnosis and therapy typically employs frequencies in the range from 1 MHz to 10 MHz. The ultrasound signals are usually generated by piezoelectric ceramic elements on which two electrodes are applied, and which have the property that when an electric voltage is applied to the electrodes, the piezoelectric element changes its physical dimensions, e.g. thickness. A piezoelectric element has a mechanical resonance frequency for this dimensional change, and the resonance frequency of the element is excited by means of electric signals. The piezoelectric elements are constructed such as to have a well-defined resonance in the above-mentioned frequency range, the resonance frequency being selected according to the purpose. By means of various known acoustic coupling media, vibrations from vibrating piezoelectric elements are conducted in the form of ultrasound into the body of a human or an animal in which the ultrasound signals propagate. When the ultrasound signals propagate in the tissue concerned, the ultrasound energy is partly absorbed in the

tissue and converted into heat, and is partly reflected and dispersed.

Ultrasound is used i.a. for image diagnostic purposes , where ultrasound signals are transmitted from an ultrasound transducer into the body of a human. These ultrasound signals consist of short ultrasound pulses, each of which has a duration of 1-5 periods of the resonance frequency. The pulses are repeated with a pulse/pause ratio of the order of 1/1000. In the pause between emission of ultrasound pulses, the ultrasound transducer is adapted to serve as a receiver of ultrasound pulses which are reflected at acoustic impedance changes in the tissue. Ultrasound pulses having relatively low ultrasound energy peak values are used here. The average intensity of the ultrasound pulses for diagnostic ultrasound does not exceed 200 W/cm^2. Owing to the long pauses between ultrasound pulses the average density of the ultrasound is very low. Time averaged intensities do not exceed 750 mW/cm^2.

Ultrasound is also used therapeutically to crush or disintegrate e.g. kidney stone and gallstone. See e.g. EP 367 117 and US 5 065 762. Devices for this purpose use focused discrete short shock waves having very high intensities. But the average value of the ultrasound intensity is relatively low, so no noticeable heating occurs. The ultrasound source generates a focused shock wave, and the shock wave results in a very strong shock (> 1000 bars) in the focal zone, which passes relatively unobstructedly through homogeneous tissue. If the focal zone of high energy intensity includes material having another acoustic impedance than the surrounding tissue, e.g. a kidney stone, the shock wave interacts with this material. In case of repeated action (2000-5000 pulses) this interaction causes a mechanical destruction or disintegration of the exposed material. Shock waves may be generated for this purpose by means of

spark discharges, microexplosions, electrohydraulic equipment or with piezoelectric elements. When piezoelectric elements are used, these are charged with a high voltage, and they are then short-circuited, whereby the resonance frequency of the elements is excited. Voltages of 10-20 kV are used for this, which for medicinal use requires special care for reasons of safety.

Continuous ultrasound waves are used for other therapeutic purposes, partly for hyperthermia, where slight heating, either localized or of entire organs, is performed by means of the absorbed ultrasound energy. Ultrasound hyperthermia is used partly in the same manner as short wave therapy for the treatment of myalgia or in connection with chemotherapy. And continuous ultrasound waves are also used for the present form of therapy, viz. pyrotherapy. See e.g. US 5 150 711.

It applies to both hyperthermia and pyrotherapy that the ultrasound has a frequency in the range 0.2 to 3.0 MHz. Low frequencies give a large penetration depth owing to poor attenuation in the tissue, while high frequencies give a good focusing owing to small wavelengths.

In pyrotherapy, the sound waves emanate convergingly from the ultrasound source which has focusing means, and a high sound pressure exists in the focal zone because of the mechanical focusing and constructive interference. The constant sound pressure of relatively high intensity leads to heating of the tissue in the focal zone. Heating to temperatures below 43 °C (hyperthermia) does not result in damage to the tissue, while the cells of the tissue are destroyed at temperatures above 60 °C (pyrotherapy). Intensities above 700 W/cm^2 and an ultrasound frequency of 1 MHz moreover results in cavitation which causes implosion of microboubles in the tissue. These microboubles grow under

the influence of the sound field until they reach a critical size where they abruptly collapse and tear holes in the surrounding cell walls.

Continuous ultrasound waves for pyrotherapy are generated by means of piezoelectric elements to which an electric voltage is applied, having a frequency corresponding to the resonance frequency of the piezoelectric elements, thereby causing the elements to vibrate with their resonance frequency.

The various uses of ultrasound devices for medical diagnosis and therapy are mentioned above according to increasing energy level, and the use for pyrotherapy thus involves the highest energy levels, which makes special requirements with respect to the electric equipment which is used for this. Relatively large and heavy electric generators and amplifiers are to be used, capable of supplying the necessary electric power, typically in the form of a square wave signal having a frequency of about 1 MHz and a power of several hundred watts. Such generators and amplifiers are typically spaced from the ultrasound head with the piezoelectric elements. The electric energy is supplied from the generator to the ultrasound head through strong, shielded cables. The very great content of higher harmonic frequencies in the square wave signal necessitates careful shielding of the electric cables, and similarly also generator and power amplifier, which process the square wave signal, are to be shielded to eliminate or reduce electromagnetic radiation.

An apparatus according to the invention, where the power amplifier handling the electric power signals at ultrasound frequency is arranged in the housing with the ultrasound head and the ultrasound generating means, provides effective electromagnetic shielding in a particularly

simple manner, as the electric wires from the power amplifier to the piezoelectric elements may hereby be made very short with a consequent lower electromagnetic radiation than in the case of long cables. The short wires also mean that power losses caused by otherwise necessary electric adapters are eliminated.

The housing with the ultrasound head may be made as a closed box of metal or another electrically conducting material and be connected electrically to the focusing lens, which may likewise be of metal, so that these parts form a substantially closed enclosure of the power amplifier and the piezoelectric elements, which are hereby completely shielded. The external wires to this housing will typically then merely be cables for power supply and signal cables passing signals at low current and voltage levels, and which will therefore not emit noticeable electromagnetic noise.

A preferred embodiment of the invention will be described below with reference to the drawing, in which

fig. 1 is a schematic view of the structure of an ultrasound head according to the invention, and

fig. 2 is a schematic view of a block diagram of a complete system according to the invention.

The ultrasound head in figure 1 comprises a housing 10 which forms a completely closed compartment. However, upwardly in the figure, the housing 10 is shown to be non-terminated, as various electric connections for the ultrasound head are provided here, as will appear from the following. The housing 10 of the ultrasound head has an outer contact face 11, which is the outer side of an ultrasound transparent diaphragm or plate 12, which is preferably

flexible and optionally has a central hole (an open bellows). In use, the contact face 11 is arranged as shown in fig. 2 against the skin of a person 60 to be treated. An ultrasound contact medium in the form of a paste or a gel, which has good transmission and contact properties for ultrasound, is applied between the contact face 11 and the person's skin. Behind the diaphragm with the contact face 11 the housing 10 accommodates a compartment 13 which, opposite the diaphragm 12, is defined by a plane-concave acoustic lens 20 whose concave side 21 faces the compartment 13. The lens 20 is made of metal, such as aluminium, or a suitable plastics material, and the lens is rotationally symmetrical about an axis 24.

A plurality of piezoelectric elements 30 are arranged concentrically about the axis of rotational symmetry 24 of the lens on the place side 22 of the lens 20, said piezoelectric elements being arranged close to the plane side 22 of the lens and in good acoustic contact with it. The piezoelectric elements are discs which are constructed to have a resonance frequency of about 1 MHz at vibrations transversely to the plane of the discs. The acoustic contact with the lens may be ensured e.g. by gluing the piezoelectric lenses 30 on the plane face 22 of the lens, or, as shown, by providing a disc 31 of cork or another air-filled and reasonably dimensionally stable material, e.g. foamed plastics, by means of which the piezoelectric elements 30 are pressed against the plane face 22 of the lens. Instead of glue, the acoustic contact medium between the piezoelectric elements 30 and the plane face 22 of the lens may be an acoustically conducting or transparent material, such as e.g. oil, fat, paste or another suitable material. A mechanical fixing block 32 of aluminium serves to mechanically fix the cork discs 31 and the piezoelectric elements 30 and to electrically connect these, since the cork discs 31 may be wound with e.g. a layer of aluminium

sheet which provides contact between the piezoelectric elements 30 and the mechanical fixing block 32. For clarity, a gap is shown here between the piezoelectric elements 30 and the cork discs 31 and between the cork discs 31 and the mechanical fixing block 32, but in practice these are positioned close to each other.

Behind the mechanical fixing block 32, the housing 10 accommodates power amplifier modules 40 which supply the piezoelectric elements 30 with electric energy in the form 1 MHz square wave signals. The preferred embodiment includes four such power amplifier modules 40, each of which supplies a plurality of piezoelectric elements 30 with up to 250 W square wave signals at the fundamental frequency of about 1 MHz. Electric contact is created between the power amplifier module 40 and the mechanical fixing blocks 32 when these are assembled mechanically.

The cork discs 31 on the rear side of each piezoelectric element 30 has an acoustic impedance owing to their content of air which causes acoustic mismatch between the mechanical fixing blocks 32 and the piezoelectric elements 30. Therefore, no ultrasound energy is transmitted up into the mechanical fixing blocks 32. When the piezoelectric elements 30 vibrate at their resonance frequency, which is chosen to be about 1 MHz in this case, the acoustic energy in the form of ultrasound will be transmitted into the plane face 22 of the lens 20, and the acoustic energy will emerge from the concave face 21 of the lens and enter the compartment 13, which is filled with an acoustically transparent transmission medium, such as e.g. water. Owing to the high energy levels special measures have to be taken to avoid cavitation, and degassed water is therefore used as a transmission medium for the ultrasound in the compartment 13. Water has an acoustic impedance which approximately corresponds to the acoustic impedance in soft part tissue

in the human body with which the contact face 11 of the diaphragm 12 gets into contact.

When acoustic contact has thus been established with a human body for treatment, the ultrasound energy will be concentrated in a focal zone 25, and the acoustic components of the apparatus and in particular the lens 20 may be dimensioned so that the focal zone 25 has a well-defined extent and location with respect to the apparatus. The energy density of the ultrasound is very high in the focal zone 25, and since the energy absorption in the tissue is proportional to the energy density, the tissue in the focal zone 25 absorbs most ultrasound energy with a consequently stronger heating than elsewhere.

The lens 20 has a central opening 26 through which an ultrasound transducer 50, in principle of a known type, runs. The ultrasound transducer 50 is used for imaging by means of ultrasound and is run to the vicinity of the diaphragm 12. The front face 51 of the ultrasound transducer 50 is an acoustic window for the transducer 50, which forms images of tissue present within a sector-shaped image field 52 by means of ultrasound in a known manner. The imaging ultrasound transducer 50 is arranged so as to be capable of rotating about the axis 24, and any axial plane can hereby be imaged in a conical volume with the sector-shaped image field 52.

The location of the focal zone with respect to the imaging ultrasound transducer 50 is well-defined, and the focal zone 25 may then be marked electronically on ultrasound images recorded by means of the transducer 50. The imaging transducer 50 is used in a known manner for localizing the place to be treated and for monitoring the treatment as it proceeds. The treatment may be monitored, and it may hereby be detected whether the place to be treated moves during

the treatment. Internal organs may be displaced, e.g. because of respiration. It may also be currently monitored whether the focal zone 25 is at the expected place in the body. This is important for reasons of patient safety.

Electric wires to the power amplifier modules 40 are not shown in fig. 1, but are run through a suitable opening in the housing 10, e.g. upwardly in the drawing. The housing 10 is in electric connection with the lens 20, and preferably in such a manner as to form a compartment which completely encloses the piezoelectric elements 30, the cork discs 31, the mechanical fixing blocks 32 and the power amplifier modules 40. The housing 10, together with the lens 20, forms a substantially completely closed electric enclosure, which provides good electromagnetic shielding.

Fig. 2 schematically shows a block diagram of a complete system for pyrotherapy according to the invention. The compartment 13, which contains degassed water, is here laterally defined by a bellows 14 causing the housing 10 with the imaging transducer 50 to be movable axially with respect to the person 60 who is to be treated. A computer system controls all functions in the system, and the user can communicate with the computer system by means of a user interface, e.g. in the form of a keyboard for the computer system. An ultrasound monitor communicates with the computer system and receives electric signals from the imaging transducer 50, and the ultrasound monitor displays ultrasound images which are recorded by the transducer 50. The ultrasound monitor displays the location of the focal zone 25 superimposed on the ultrasound image, so that it can be currently observed whether the focal zone is placed correctly with respect to the tissue to be treated.

By means of a lens/patient positioning system the focusing lens 20 (and the housing 10) may be positioned correctly

with respect to the patient 60, such that the focal zone 25 may be placed accurately in the tissue to be treated. This is checked and monitored on the ultrasound monitor. If it is found on the ultrasound monitor that the focal zone is not in the region to be treated, or the focal zone is to be moved to a new region, the position of the lens is adjusted by means of the positioning system monitored by the ultrasound monitor.

A DC power supply is arranged outside the housing 10 and supplies DC energy to the power amplifier modules 40 in the housing 10. A control signal generator, which is controlled by the computer system, supplies control signals to the power amplifier modules 40. The control signals from the control signal generator are here in the form of logical signals or ON/OFF signals, which control the power amplifier modules 40 to either operate at full, continuous power or to be disconnected. The power amplifier modules 40 comprise an ultrasound frequency generator which, when the control signals are ON, generates a 1 MHz square wave signal which is amplified and passed to the piezoelectric elements 30, and when the control signal is OFF, no such ultrasound signal is generated. All high energy ultrasound signals are thus contained and enclosed in the housing 10, which forms an electric shield.

The degassed water, which serves as an ultrasound transmission medium in the compartment 13, is degassed in a degassing apparatus and is circulated between this system and the compartment 13. The circulating degassed water may possibly be used for cooling the power amplifier modules 40.

Integration of the power amplifier modules 40 in the housing 10 ensures that operation takes place everywhere at relatively low voltages, typically below ± 50 V, and all

high power ultrasound signals are completely enclosed and shielded in the housing 10. This results in an extremely effective shielding and means that the high energy ultrasound signals are not to be passed through long cables which must necessarily be shielded owing to the content of high frequencies in the signals. Accordingly, the electromagnetic radiation is extremely low, and the entire apparatus therefore has high electromagnetic compatibility. Further, all electric signals are kept at the rear side of the lens 20, which, together with the housing 10, is held at a fixed zero reference potential. The patient is therefore not subjected to electric voltages, which results in a high safety for the patient.

P a t e n t C l a i m s :

1. An apparatus for non-invasive tissue destruction by means of continuous focused ultrasound of high intensity, said apparatus comprising

an ultrasound head in a housing having a contact face to engage a patient's skin,

an ultrasound generating element in the housing,

focusing means arranged in the housing for focusing ultrasound from the ultrasound generating element in a focal zone outside the housing by transmission of ultrasound through the contact face,

a power amplifier adapted to supply the ultrasound generating element with electric energy at ultrasound frequencies,

a power supply for supplying the power amplifier with electric energy,

c h a r a c t e r i z e d in that the power amplifier is arranged in the housing.

2. An apparatus according to claim 1, c h a r a c t e r i z e d in that the power supply is arranged outside the housing.

3. An apparatus according to claim 2, c h a r a c t e r i z e d in that the power amplifier is adapted to generate the electric signals at ultrasound frequencies in response to control signals, and that a control signal generator is provided outside the housing to generate the control signals, and that these are passed to the power generator.

4. An apparatus according to claims 2-3, c h a r a c t e r i z e d in that the focusing means are a plane-concave lens having ultrasound generating piezoelectric elements at the plane side of the lens, and that this plane side forms a wall of a compartment in the housing, and that the power amplifier is arranged in said compartment.

5. An apparatus according to claims 1-4, c h a r a c t e r i z e d in that the lens is of an electrically conducting material, and that the compartment in the housing is defined by walls of an electrically conducting material in electric connection with the lens so that the power amplifier and the piezoelectric elements are substantially enclosed in electrically conducting material.

6. An apparatus according to claims 1-5, c h a r a c t e r i z e d in that the piezoelectric elements are kept engaged with the plane side of the lens by means of an air-filled, dimensionally stable material.

7. An apparatus according to claims 1-6, c h a r a c t e r i z e d in that the power supply supplies the power amplifier with electric energy at an adjustable voltage.

8. An apparatus according to claim 7, c h a r a c t e r i z e d in that the power amplifier supplies the ultrasound generating element with electric energy whose level depends on the adjustable voltage.

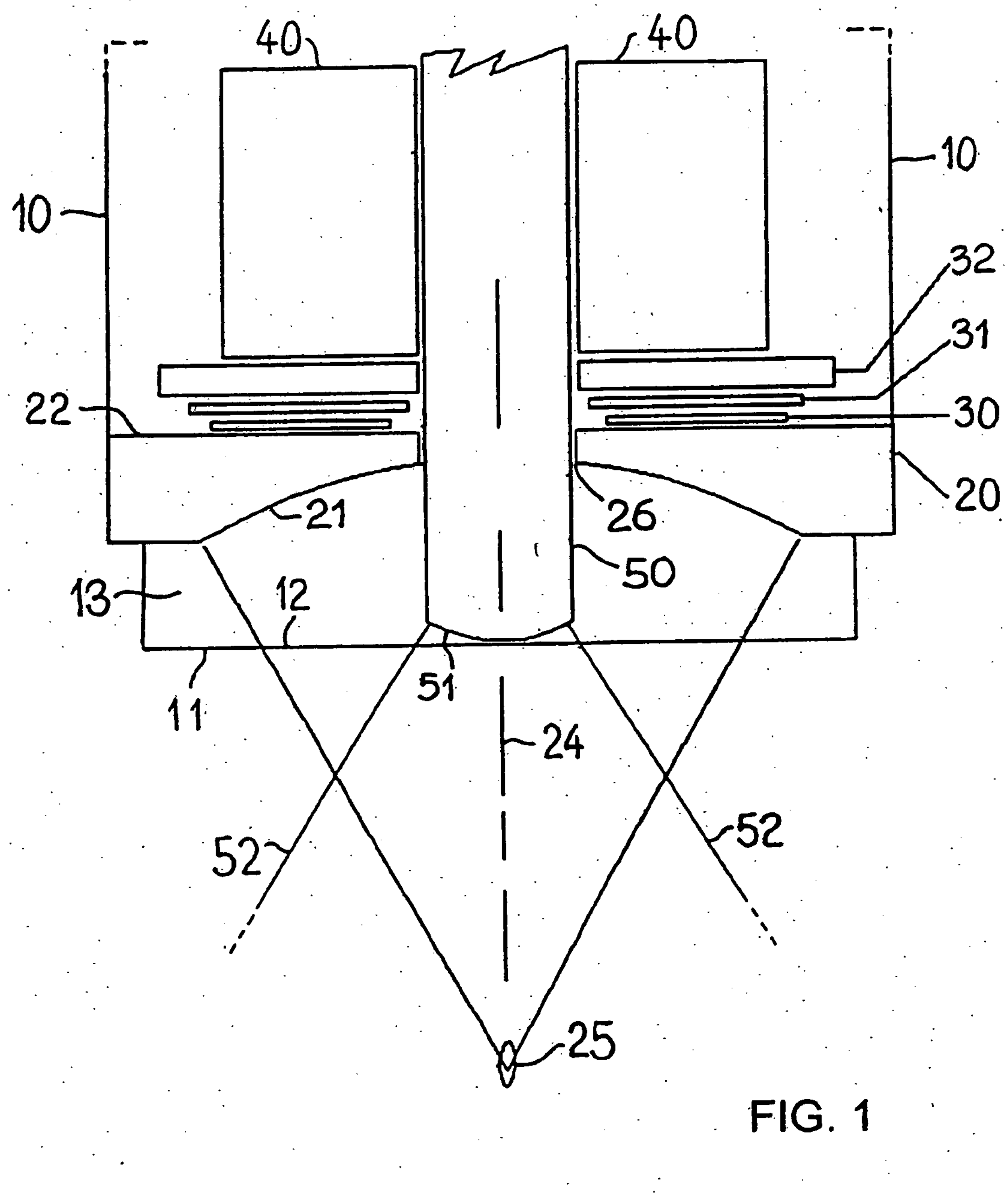
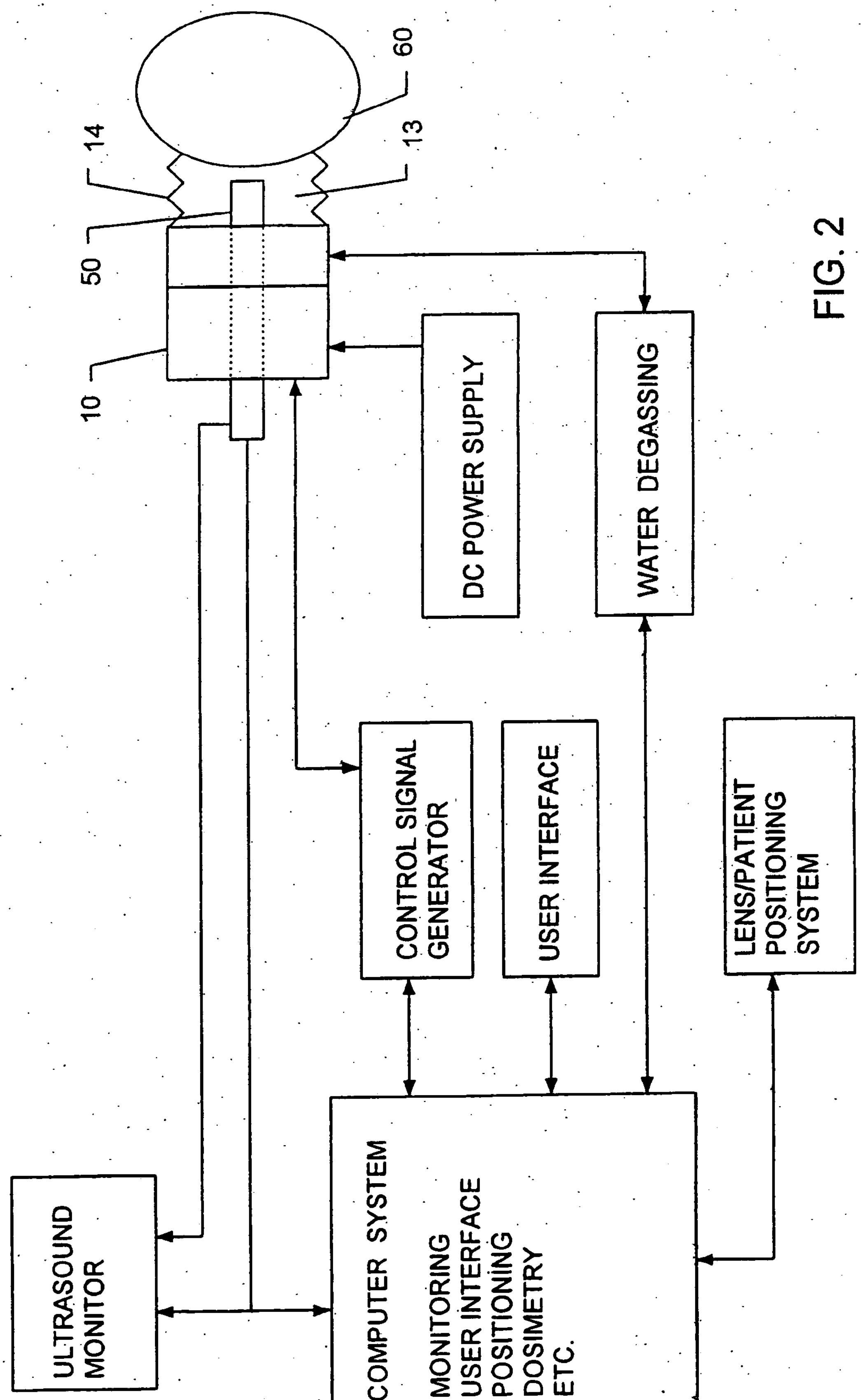


FIG. 1

2/2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14
13
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DC POWER SUPPLY
WATER DEGASSING
CONTROL SIGNAL GENERATOR
USER INTERFACE
LENS/PATIENT POSITIONING SYSTEM
ULTRASOUND MONITOR
COMPUTER SYSTEM
MONITORING
USER INTERFACE
POSITIONING
DOSIMETRY
ETC.

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 95/00102

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/36, A61B 17/22
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61N, G10K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP, A1, 0278303 (SIEMENS AKTIENGESELLSCHAFT BERLIN UND MUNCHEN), 17 August 1988 (17.08.88), see the whole document	1
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A	EP, A1, 0280088 (SIEMENS AKTIENGESELLSCHAFT BERLIN UND MUNCHEN), 31 August 1988 (31.08.88), see the whole document	1
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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT
Information on patent family members

03/05/95

International application No.
PCT/DK 95/00102

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A1- 0278303	17/08/88	US-A- 4865041	12/09/89
		DE-A- 3703333	18/08/88
EP-A1- 0280088	31/08/88	US-A- 4926857	22/05/90